

BEFORE THE DEPARTMENT OF LIVESTOCK
OF THE STATE OF MONTANA

In the matter of the amendment of) NOTICE OF PROPOSED AMENDMENT
ARM 32.2.403 pertaining to)
diagnostic laboratory fees) NO PUBLIC HEARING
) CONTEMPLATED

TO: All Concerned Persons

1. The Department of Livestock proposes to amend the above-stated rule.

2. The Department of Livestock will make reasonable accommodations for persons with disabilities who wish to participate in the rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Livestock no later than 5:00 p.m., March 8, 2021, to advise us of the nature of the accommodation that you need. Please contact Executive Officer, Department of Livestock, 301 N. Roberts St., Room 304, P.O. Box 202001, Helena, MT 59620-2001; telephone: (406) 444-9525; TTD number: 1 (800) 253-4091; fax: (406) 444-4316; e-mail: MDOLcomments@mt.gov.

3. The rule as proposed to be amended provides as follows, new matter underlined, deleted matter interlined:

32.2.403 DIAGNOSTIC LABORATORY FEES (1) and (2) remain the same.

(3) MVDL services and fees:

(a) Clinical Microbiology/Bacteriology:

Test	Fee
aerobic culture	\$20.00
aerobic culture - additional isolate	\$10.00
anaerobic culture	\$24.00
anaerobic culture - additional isolate	\$10.00
antibiotic sensitivity - per isolate	\$15.00
brucella culture	\$20.00
campylobacter culture	\$16.00
dermatophyte culture	\$30.00
direct microscopy	\$10.00
fecal occult blood	\$11.00
fungal culture	\$30.00
listeria culture	\$24.00
mycoplasma culture	\$20.00
salmonella culture	\$20.00
salmonella enteritidis confirmatory culture	\$28.00

tritrichomonas foetus culture	\$7.00
<u>giardia antigen SNAP test</u>	<u>\$18.00</u>

(b) through (f) remain the same.

(g) Molecular Diagnostics (PCR)

Test	Fee
avian influenza (AI)	\$40.00
Bovine coronavirus/rotavirus multiplex	\$45.00
bovine virus <u>viral</u> diarrhea <u>virus</u> (BVDV):	
individual samples (ear notch samples)	\$40.00
MVDL pooled (ear notch samples)	\$65.00
E. coli - K99	\$40.00
bovine respiratory disease viral PCR panel	\$50.00
Classical Swine Fever, Foot & Mouth Disease, Vesicular Stomatitis Virus, Swine Influenza Virus, or Avian Paramyxovirus PCR	\$40.00 each
mycobacterium avium paratuberculosis (Johne's):	
individual sample	\$36.00
MVDL pooled (up to 5 feces samples)	\$42.00
salmonella enteritidis PCR	\$36.00
tritrichomonas foetus:	
individual sample	\$30.00
MVDL pooled (up to 5 samples)	\$55.00
<u>coxiella and chlamydia PCR</u>	<u>\$36.00</u>
<u>mycoplasma bovis PCR</u>	<u>\$36.00</u>

(h) through (k) remain the same.

(l) Virology

Test	Fee
canine parvovirus SNAP	\$30.00
fluorescent antibody (FA) testing - per agent:	
bovine coronavirus (BCV)	\$11.00
bovine respiratory syncytial virus (BRSV) SN	\$11.00
bovine virus <u>viral</u> diarrhea <u>virus</u> (BVDV)	\$11.00
canine distemper (CDV)	\$11.00
canine parvovirus (CPV)	\$11.00
equine herpesvirus (EHV)	\$11.00
feline panleukopenia (FPLV)	\$11.00
feline infectious peritonitis (FIP)	\$11.00
feline herpes (FHV)	\$11.00
infectious bovine rhinotracheitis (IBR)	\$11.00
leptospira	\$11.00

	parainfluenza - 3 Virus (PI-3)	\$11.00
	porcine parvovirus (PPV)	\$11.00
	chronic wasting disease IHC	\$34.00
	chronic wasting disease ELISA	\$14.00
	virus isolation (livestock only)	\$34.00
	<u>bovine viral diarrhea virus (BVDV) antigen SNAP test</u>	<u>\$7.00</u>
	<u>equine virus arteritis (EVA) virus neutralization test</u>	<u>\$16.00</u>

(m) remains the same.

AUTH: 81-1-102, 81-2-102, MCA

IMP: 81-1-301, 81-1-302, 81-2-102, MCA

REASON: The department is proposing to amend the above-stated rule with five new tests and associated fees resulting in improved quality of work for clients, decreased turnaround time for test results, a reduction in potential legal and regulatory exposure, clients being offered more diagnostically reliable and cost-effective testing options, the potential for more federal funding, lowered overhead costs, and greater operational flexibility and efficiency.

Bovine Viral Diarrhea Virus BVDV SNAP Test

The BVDV snap test would take the place of any single animal submissions that we currently perform ELISA, PCR or virus isolation on (>2000 tests in FY20). In these single animal cases, the snap test will drastically reduce our turnaround time and lab time investment from several hours/days to less than an hour. The following table illustrates the projected time to complete testing within the lab section, projected turnaround time from sample receipt to issuing results, and the associated test fee.

Test	Test Time	Turnaround Time (days)*	Test Fee
BVDV ELISA	4-6 hours	1-2	\$6.00
BVDV PCR	8 hours	2-3	\$40.00
BVDV Virus Isolation	14 days	21	\$34.00
BVDV SNAP	30 minutes	1	\$7.00

* Based on normal operational flow

In addition to time savings for MVDL staff and decreased turnaround time for clients/producers in Montana, the proposed BVDV SNAP test fee of \$7/test will provide a significant savings over our current BVDV PCR test (\$40/test) and BVDV virus isolation assay (\$34/test).

The main benefit to the BVDV SNAP test would be when we receive a single test submission or a low number (1-5) of test submissions. The SNAP test will result in a significantly faster turnaround time for a limited number of samples and will reduce the time burden on our lab technicians for these cases. Once the samples numbers get higher (such as the testing of a large herd) it may be more efficient to do the

ELISA or PCR using the pooling option. The availability of the SNAP test option will allow our staff to mix and match testing methodologies to provide greater operational flexibility and efficiency.

Equine Virus Arteritis (EVA) Virus Neutralization Test

EVA is a National Animal Health Laboratory Network (NAHLN) scope disease and thus, we are proposing to add this test as it is in the best interest of the MVDL to become qualified to perform this diagnostic test as it increases our standing with NAHLN. The number of NAHLN scope diagnostic tests a lab is qualified to perform is an input into a capability matrix which determines the amount of annual federal funding an NAHLN lab receives.

The EVA test utilizes most of the same reagents we currently have on hand and use for other serum neutralization (SN) tests, minus the cell line and virus. The upfront investment for the additional components is \$287. Once set up and qualified, we will have exceedingly low supply overhead costs since the virus and cell line can be propagated and stored indefinitely going forward.

Giardia SNAP Test

The MVDL is currently offering a giardia ELISA test that is only validated for use in humans and is not validated for use in diagnosing animal samples. We are proposing to switch our giardia test method to the IDEXX SNAP test, which is a USDA approved diagnostic assay. The giardia ELISA is twice as expensive (\$34/test) as the giardia SNAP test (\$18/test), and the bench time required for the ELISA (60 minutes) is double that of the SNAP test (30 minutes).

In summary, switching to a USDA licensed test will reduce potential legal and regulatory exposure for the Department of Livestock compared to using an unvalidated diagnostic test. By offering this test, we will provide our clients with a more diagnostically reliable and cost-effective testing option.

Mycoplasma Bovis PCR Test

Currently, the MVDL has no diagnostic test capable of determining mycoplasma speciation. Since most of our clients know that we cannot speciate mycoplasma bovis, we suspect a lot of them either have us culture for mycoplasma in general, or they send samples directly to other labs for speciation. For mycoplasma testing specifically, often this test is incorporated as part of a respiratory PCR panel at other laboratories, something that we refer out of state with regularity. Offering this test would significantly improve the quality of our diagnostic workups for respiratory disease.

Also, offering a PCR test would result in a turnaround time for our clients of 2-3 days rather than the >7 days for a mycoplasma culture. Once the assay is online and qualified, the MVDL could consider incorporating it into a respiratory panel, a diagnostic test offering that will primarily benefit cattle producers during the fall and winter.

Coxiella/Chlamydophila PCR

The MVDL has received occasional interest from our clients regarding this testing, specifically in sheep. When we tell them we cannot currently provide this testing, we typically do not receive samples for this testing, since clients know we are going to refer it out.

These two kits use the same reagents and platforms for extraction and the expendables and turnaround time would be the same as any of our other routine PCR tests. The time and investment we would need to bring these tests online is anticipated to be the cost of verifying the tests, something we do on a regular basis for new tests, new kits, changes in reagents/suppliers, or any other material change to a diagnostic assay. Offering these assays would significantly improve the quality of our workups for livestock abortions during the winter/spring reproductive season and lay the groundwork for future incorporation of these assays into a PCR abortion panel.

The equine virus arteritis (EVA) virus neutralization test (\$16), the mycoplasma bovis PCR test (\$36), and the Coxiella/Chlamydophila PCR test (\$36) do not replace any existing tests, and the overall economic impact from the new fees are expected to be negligible due to low test numbers. The giardia SNAP test will replace a \$36 test with an \$18 test, resulting in a cumulative decrease, but this decrease is expected to be negligible due to low test numbers. The \$7 BVDV SNAP test will replace three prior BVDV tests, the highest volume of which is the \$6 BVDV ELISA test (<2000 in FY20), resulting in less than a \$2000 cumulative annual increase. This increase is anticipated to be offset by the BVDV SNAP test also replacing the \$40 BVDV PRC test and the \$34 BVDV virus isolation test, but this effect is expected to be negligible due to low test numbers. There are approximately 600 veterinary submitters, at least 150 nonveterinary submitters, and 100 governmental entities only minimally affected by the proposed fee adjustments.

4. Concerned persons may submit their data, views, or arguments in writing concerning the proposed action to Department of Livestock, 301 N. Roberts St., Room 306, P.O. Box 202001, Helena, MT 59620-2001, by faxing to (406) 444-1929, or by e-mailing to MDOLcomments@mt.gov, to be received no later than 5:00 p.m., March 12, 2021.

5. If persons who are directly affected by the proposed action wish to express their data, views, and arguments orally or in writing at a public hearing, they must make a written request for a hearing and submit this request along with any written comments they have to the same address as above. The written request for hearing must be received no later than 5:00 p.m., March 12, 2021.

6. If the department receives requests for a public hearing on the proposed action from either 10 percent or 25, whichever is less, of the persons directly affected by the proposed action; from the appropriate administrative rule review committee of the Legislature; from a governmental subdivision or agency; or from an association having not less than 25 members who will be directly affected, a public

hearing will be held at a later date. Notice of the public hearing will be published in the Montana Administrative Register. Ten percent of those entities directly affected has been determined to be 85 based upon approximately 600 veterinary submitters, at least 150 nonveterinary submitters, and 100 governmental entities affected by the proposed fee adjustments.

7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 4 above or may be made by completing a request form at any rules hearing held by the department.

8. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

9. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rule will not significantly and directly impact small businesses.

/s/ Michael S. Honeycutt
Michael S. Honeycutt
Executive Officer
Board of Livestock
Department of Livestock

BY: /s/ Cinda Young-Eichenfels
Cinda Young-Eichenfels
Rule Reviewer

Certified to the Secretary of State February 2, 2021.